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Vista IP Law Group LLP 2040 MAIN STREET, 9TH FLOOR IRVINE, CA 92614			EXAMINER GEDEON, BRIAN T	
			ART UNIT	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

HH

Office Action Summary

Application No.

10/799,271

Applicant(s)

GARABEDIAN ET AL.

Examiner

Brian T. Gedeon

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 August 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-47 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 and 18-47 is/are rejected.
- 7) ☒ Claim(s) 11-17 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 4/22/2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

1. Acknowledgement is made of the Applicant's arguments submitted to the Office on 4 August 2006. In the previous Office Action 25 May 2006, claims 1-125 were addressed, wherein claims 20-23, 33-36, 66-68, 77, 78, 103-106, 124, and 125 were objected to for improper dependent form; claims 1-7, 9, 10, 18-29, 31-54, 56, 57, 65-74, 76-90, 92, 93, 101-112, 114, 115, and 123-125 were rejected under 35 U.S.C. 103(a); and claims 8, 11-17, 30, 55, 58-64, 75, 91, 94-100, 113, and 116-122 were objected to as being allowable but relying on a rejected base claim.
2. The Examiner also acknowledges a preliminary amendment filed 3 December 2004 canceling claims 48-125 from consideration; rejections regarding claims 48-125 in the previous Office action have been withdrawn. Therefore, claims 1-47 remain pending, and will be addressed in this action.

Oath/Declaration

3. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

It does not state that the person making the oath or declaration acknowledges the duty to disclose to the Office all information known to the person to be material to patentability as defined in 37 CFR 1.56.

Specifically, the oath/declaration do not have the correct statement with respect to the duty to disclose.

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CORRECT STATEMENTS should read:

- "I acknowledge the duty to disclose information which is material to patentability of this application in accordance with Title 37, Code of Federal Regulations Section 1.56."

INCORRECT STATEMENTS:

- "I acknowledge the duty to disclose information which is material to the examination of this application in accordance with Title 37, Code of Federal Regulations Section 1.56(a)"
- "I acknowledge the duty to disclose information which is material to the patentability of this application in accordance with Title 37, Code of Federal Regulations Section 1.56(a)"
- "I acknowledge the duty to disclose information which is material to the examination of this application in accordance with Title 37, Code of Federal Regulations Section 1.56"

Appropriate correction is required.

Claim Objections

4. Applicant's response to the objections made against claims 20-23, 33-36, 66-68, 77, 78, 103-106, 124, and 125 has been considered and found to be persuasive. The Examiner withdraws the objections made against these claims.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States

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only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 1-2, 4-10, 18, 19, and 24-32 are rejected under 35 U.S.C. 102(e) as being anticipated by Vinup et al. (US Patent no. 7,072,719).

In regard to claims 1 and 24, Vinup et al. disclose a neurological stimulation system 20 with stimulation leads 24 and 26 with interlocking elements 23, col 1 lines 28-39. Figures 2-5 show a plurality of medical leads which allow for implantation of paddle or surgical style leads using percutaneous methods without the use of a large needle or introducer, col 2 lines 40-49. The leads are axially engaged to one another. The leads are inserted by inserting a first lead body into a predetermined position, then guiding a second lead body using the first lead body as a guide, col 3 line 55 – col 4 line 2. The lead bodies are axially engaged to one another by a wide variety of complementary coupling geometries, such as a rail and groove embodiment as depicted in figures 6a-7b, col 3 lines 46-54. In view of the insertion of the second lead body using the first lead body as a guide, it is interpreted as the second lead being slidably inserted along the first lead, wherein the leads can be slidably engaged along the rail and groove coupling mechanism.

In regard to claims 2 and 25, the lead bodies are cylindrically shaped, figures 6a-6c.

In regard to claims 4, 5, 7, 26, 27, and 29, the stimulation leads of Vinup et al. have at least one electrode, col 2 lines 50-58.

In regard to claims 6 and 28, figures 2-4 of Vinup et al. show the electrodes 34 facing in a single direction when the leads are engaged with one another.

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In regard to claims 8, 9, 30, and 31, the complementary coupling mechanisms 23, are rail and groove embodiment, extending axially along the leads, col 3 lines 46-54.

In regard to claim 10, figures 2-5 show the first and second leads being of different lengths.

In regard to claim 18, figures 2-4, 6a-6c, and 9a-9c, shows various embodiments where a plurality of leads can be engaged to one another by means of complementary coupling mechanisms being axially located on both sides of a single lead.

In regard to claims 19 and 32, a neurological stimulator 22 is coupled to the stimulation leads, col 2 lines 29-32.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 3, 20-23 and 33-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vinup et al. (US Patent no. 7,072,719) as applied to claims 1 and 24, and further in view of Cross, Jr. et al. (US Patent no. 6,578,733 – hereinafter Cross).

In regard to claim 3, Vinup et al. disclose the claimed invention with the exception of specific dimensions for the cross-sectional area of the first and second elongated bodies. It would have been obvious to one with ordinary skill in the art at the time the invention was made to utilize 5 mm or less for the said elongated bodies since our

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reviewing courts have held that where the only difference between the prior art and the claims was a recitation of relative dimensions of the claimed device and a device having the claimed relative dimensions would not perform differently than the prior art device, the claimed device was not patentably distinct from the prior art device. *Gardner v. TEC Systems, Inc.*, 725 F.2d 1338, 220 USPQ 777 (Fed. Cir. 1984), cert. denied, 469 U.S. 830, 225 USPQ 232 (1984).

In regard to claims 20, 22, 33, 35, 37, 39, and 46, Vinup et al. describe the invention as claimed including inserting a first stimulation lead at a predetermined position, then guides at least a second stimulation lead along the first stimulation lead, wherein the leads are coupled together by means of a complementary coupling mechanism, col 3 lines 46-67. The leads are configured to be coupled together and stimulate neurological tissue (i.e., nerves or muscle tissue) in a desired location, col 2 lines 33-36. However, Vinup et al. do not teach that the leads are inserted into the epidural space around the spinal cord. Cross, in a similar field of endeavor, discloses a percutaneous surgical lead, wherein two lead bodies 12 and 14 are coupled together and inserted into the spinal cord. Cross also teaches that stimulation of the spinal cord often is accomplished by implanting medical leads into the epidural space of the spinal cavity, col 1 lines 20-23. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Vinup et al. with the teachings of Cross since Vinup et al. teach that the stimulation lead can percutaneously be implanted in a desired spot to stimulate nerve tissue and Cross teaches that it is

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known in the art to stimulate nerve tissue in the epidural space of the spinal cord by means of an electrical lead.

In regard to claims 21, 34, and 38, Vinup et al. teach that the stimulation leads are percutaneously inserted into the desired space, col 2 lines 40-49.

In regard to claims 23, 36, and 41, Vinup et al. teach that neurological stimulation is known to treat chronic pain, col 1 lines 13-18.

In regard to claim 40, the stimulation leads of Vinup et al. are connected to a neurological stimulator 22, col 2 lines 28-39.

In regard to claim 42-44, the objective of Vinup et al. is to apply electrical stimulation to neural tissue in any desired location, col 28-39. Figure 1 shows the leads implanted near the spine.

In regard to claim 45, figures 2-4, 6a-6c, 9a-9b of Vinup et al., show a plurality of leads, including three, engaged to one another.

In regard to claim 47, Vinup et al. teach that a needle or introducer, col 3 lines 57-60 introduce the stimulation leads.

Allowable Subject Matter

9. Claims 11-17 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

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10. The indicated allowability of claims 8 and 30, is withdrawn in view of the newly discovered reference(s) to Vinup et al. Rejections based on the newly cited reference(s) are above.

Response to Arguments

11. Applicant's arguments, see Remarks, filed 4 August 2006, with respect to the rejection(s) of claim(s) 1-7, 9, 10, 24-29, 31, and 32, and 31-47 under 35 U.S.C. 103(a) in view of Cross Jr. et al. (US Patent no. 6,587,733) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Vinup et al. (US Patent no. 7,072,719).

12. Applicant's arguments, see Remarks, filed 4 August 2006, with respect to the rejection(s) of claim(s) 18, 20-23, 33-44, 46, and 47 under 35 U.S.C. 103(a) in view of Cross Jr. et al. (US Patent no. 6,587,733) and Morgan et al. (US Patent no. 6,988,007) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Vinup et al. (US Patent no. 7,072,719).

Conclusion

13. In view of the new grounds of rejection, this Office action is NON-FINAL.

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14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian T. Gedeon whose telephone number is (571) 272-3447. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela D. Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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